***United States Court of Appeals***

***for the Second Circuit***


# APPELLANT'S BRIEF

75-7143


To be argued by
J. Leo Coupe,
Utica, New York

In The

UNITED STATES COURT OF APPEALS

For The Second Circuit

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No. 75-7143

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B P/S

MALACHY J. SMYTH and
LUCY SMYTH,

Plaintiffs-Appellants,

vs.

THE UPJOHN COMPANY,

Defendant-Appellee.

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On Appeal from the United States District Court

For the Northern District of New York

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# APPELLANTS' BRIEF

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## QUESTION PRESENTED

Did the trial court err in excluding from evidence proof of warnings made subsequent to the date of injury under the doctrine of post-occurrence changes?

## PRELIMINARY STATEMENT

This is an appeal from a judgment of the District Court for the Northern District of New York based upon a jury verdict in favor of the defendant on January 27, 1975.

The action is for negligence against the manufacturer and distributor of the antibiotic drug Lincocin (lincomycin) based upon the defendant's failure to warn the medical profession, and particularly, the plaintiff Malachy J. Smyth, a physician, of the harmful side-effects of the drug. His is the principal action. That of his wife Lucy is derivative.

The facts of the case are as follows:

On February 3, 1970, the plaintiff Dr. Malachy J. Smyth ingested the usual recommended dosage of Lincocin for a sinusitis which could not be cultured because of the lack of oral or nasal discharge. After several days he developed diarrhea, discontinued the drug, and eventually administered mycostatin as a specific against a monilial infection which, he thought, was the aftermath of the antibiotic thereapy.

In spite of the daily intake of mycostatin, his condition became progressively worse. He eliminated large casts of mucous from the bowel, suffered extensive frank bleeding from the reaction, and was eventually hospitalized from March 19, 1970, to April 15, 1970. A drastic increase in the dosage of mycostatin removed all symptoms of monilial infection, but he remained in a severely debilitated condition, having lost approximately 50 pounds.

During this time he underwent a barium enema with x-rays which showed abnormalities of the colon indicative of ulcerative colitis. He was also examined by sigmoidoscope. That examination disclosed no pathology or abnormality of the sigmoid or rectum. However, there was a large ulcer at the posterior anus the origin of which the physician who performed the sigmoidoscopy was unable to determine.

He was later hospitalized for a week in June, 1970, at which time he received several blood transfusions. During November, 1971, he consulted a gastroenterologist who prescribed Azulfidine. He gradually improved and began to regain his normal weight.

Dr. Harold Heintz of Utica performed barium x-ray studies during November, 1970, and September, 1971. These studies indicated that Dr. Smyth had been suffering from ulcerative colitis. He and his physician, Dr. Dwyer, testified that in their opinion the cause of the colitis was the ingestion of the Lincocin.

At the trial the plaintiffs introduced 50 exhibits (Appendix, Exhibits 16 - 65) which were furnished by defendant from its files

kept in its headquarters at Kalamazoo, Michigan. These exhibits consisted of documents which showed that Upjohn knew prior to the date when Dr. Smyth took the drug on February 3, 1970, that there were at least 57 cases of colitis following Lincocin therapy. In at least one case a subtotal colectomy had to be performed (Exhibit 21), in another a colon resection (Exhibit 22), and in several cases the symptomatology was of long duration (5 mos., Exhibit 18; 15 mos., Exhibit 54; 1 yr., Exhibit 54). In all reported cases the patient was acutely ill, and, in one reported case (Exhibit 17), the patient died of a heart attack while at stool.

PHYSICIANS' DESK REFERENCE AND

PACKAGE INSERT WARNINGS

A review of the Physicians' Desk References (herein "PDR") and package inserts from the year 1970 to date will demonstrate our contention that the warning was not sufficient in view of the fact that Upjohn had at least 57 adverse reactions reports of colitis.

The 1970 PDR (Appendix - Exhibit 11) at page 1385 reads as follows:

"Warning: Cases of severe and persistent diarrhea, some with blood and mucus in the stools have been reported and at times have necessitated discontinuance of the drug. (This is in small italic type.) This side effect usually has been associated with the oral dosage form but has occasionally been reported following parenteral therapy."

It also continues:

"Adverse Reactions:

"Gastrointestinal --Glossitis, stomatitis, nausea, persistent diarrhea, enterocolitis and pruritus ani."

This is the only place where enterocolitis is mentioned in the 1970 PDR. The warning is nonexistent since the gastrointestinal symptomatology runs a gamut from ingestion to excretion. This section might as well have said "gastrointestinal problems may be encountered."

The PDR Supplement C/70 (Appendix - Exhibit 11A) which was issued after Upjohn had knowledge of Dr. Smyth's case changed the warning to provide as follows (p. C32):

"Warnings: Cases of severe and persistent diarrhea have been reported and have at times necessitated discontinuance of the drug. This diarrhea has been occasionally associated with blood and mucus in the stools and has at times resulted in an acute colitis. (Emphasis supplied by us.) This side effect usually has been associated with the oral dosage form but occasionally has been reported following parenteral therapy. Although no cross sensitivity with other antibiotic agents has been demonstrated, a careful inquiry should be made concerning previous sensitivities to drugs and other allergens."

It should be noted that this is the first time that "acute colitis" has been mentioned in the warning section.

Supplement C goes on to state:

"Adverse Reactions:

"Gastrointestinal -- Glossitis, stomatitis, nausea, vomiting. Persistent diarrhea, enterocolitis and pruritus ani. (See "Warnings").

This is the first time that the PDR refers the physician back to the warnings section.

It should be noted that again "enterocolitis" is mentioned in the "Adverse Reactions: section but that the warning is reinforced by the use of the words "acute colitis" in the "Warnings" section.

In the PDR for 1972 (Appendix - Exhibit 66) we find the following (p. 1459):

"WARNINGS: CASES OF SEVERE AND PERSISTENT DIARRHEA HAVE BEEN REPORTED AND HAVE AT TIMES NECESSITATED DISCONTINUANCE OF THE DRUG. THIS DIARRHEA HAS BEEN OCCASIONALLY ASSOCIATED WITH BLOOD AND MUCUS IN THE STOOLS AND HAS AT TIMES RESULTED IN AN ACUTE COLITIS. THIS SIDE EFFECT USUALLY HAS BEEN ASSOCIATED WITH THE ORAL DOSAGE FORM BUT OCCASIONALLY HAS BEEN REPORTED FOLLOWING PARENTERAL THERAPY." This warning is to be found in bold block type. Again under the "Adverse Reactions: section, we find "Gastrointestinal -- Glossitis, stomatitis, nausea, vomiting. Persistent diarrhea, enterocolitis and pruritus ani. (See "Warning")."

In the 1974 PDR (Appendix - Exhibit 66A) the "Warning" section is the same. The "Adverse Reactions" section is the same except that in this instance the word "Warning" is in bold block type.

In Supplement B of the 1974 PDR (Appendix - Exhibit 67) a very substantial type of warning is indicated. It states as follows (p. B48):

"Warning: Immediately preceding Description and following the product title, a boxed WARNING statement has been inserted. This replaces the previous paragraph in the Warnings section relative to diarrhea and colitis. The new statement reads as follows:

WARNING

"Severe and persistent diarrhea, which may be accompanied by blood and mucus, and which may be associated with changes in large bowel mucosa diagnosed as "psuedomembranous colitis", has been reported in association with the administration of Lincocin (lincomycin hydrochloride). When significant diarrhea occurs (usually more than 5 bowel movements daily), the drug should be discontinued or, if necessary, continued only with close observation of the patient (large bowel endoscopy has been recommended). Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed promptly with fluid, electrolyte

and protein supplementation as indicated. Antiperistaltic agents--opiates, meperidine and diphenoxylate with atropine may prolong and/or worsen the condition. Systemic corticoids retention enemas may help relieve the colitis. Other causes of colitis should also be considered. Note: Diarrhea has been observed to begin up to several weeks following cessation of therapy with Lincocin. The physician must be alert to this possibility."

This is the last Supplement available. In the main book for 1974 under "Adverse Reactions" it is stated (p. 1498):

"Gastrointestinal -- Glossitis, stomatitis, nausea, vomiting. Persistent diarrhea, enterocolitis and pruritus ani. (See "WARNINGS")."

It is significant that throughout the entire PDR history from 1970 to date the "Adverse Reactions" section has remained the same but the "Warning" section has changed drastically since 1970. This points up our contention that the mere mention of enterocolitis together with every other possible inflamation of the gastrointestinal tract is not in itself a warning and that the warning intended for the physician is that under the section so labeled.

# ARGUMENT

## POINT I

### THE TRIAL COURT ERRED IN REFUSING TO ADMIT THE PHYSICIANS' DESK REFERENCES PUBLISHED SUBSEQUENT TO THE ACCIDENT.

The trial court refused to permit plaintiffs to introduce those sections of the PDR covering Lincocin which had been published after February 3, 1970, the date Dr. Smyth took the drug, on the ground that this was evidence of a subsequent repair, and, therefore, not admissible to prove negligence.

It is conceded that the law of New York is that evidence of repairs made subsequent to an accident is not admissible to prove negligence.

Corcoran v. Village of Peekskill, 108 N.Y. 151, 15 N.E. 309 (1888)

The rationale for this rule is that such evidence is:

(1) Contrary to public policy in that it penalizes a careful person who would be impelled to make repairs to a dangerous condition from doing so for fear of being held liable by reason of such action. Such repairs should be encouraged to prevent accidents which might follow the original accident, and

(2) Such evidence is not relevant to the question of negligence because experience gained since the negligent event may well have caused the actor to improve a negligent condition. Subsequent experience would call for subsequent repairs. Without such hindsight no action would be required.

We respectfully maintain that such reasoning does not apply to a products liability case involving an antibiotic drug.

21 USCA 357(g)* provides for regular reports to be furnished by the manufacturer and distributor of an antibiotic drug in conformity with regulations promulgated by the Secretary of Health, Education and Welfare. The adverse reaction reports (Exhibits 16-65) almost without exception contain a communication from Upjohn to the FDA

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*Records and reports; professional ethics and interests of patients; examination of data; access to records

(g)(1) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect to such drug, as the Secretary may by general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to make, or to facilitate, a determination as to whether such certification or release should be rescinded or whether any regulation issued under this section should be amended or repealed: Provided, however, That regulations and orders issued under this subsection and under clause (3) of subsection (d) of this section shall have due regard for the professional ethics of the medical profession and the

concerning each case of colitis although in many cases (Exhibits 18, 20, 24, 25, 27, 28, 31, 32, 38, 39, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 61, 64, and 65) Upjohn referred to colitis as "diarrhea," expecially during the early years of its distribution.

If therefore, a pharmaceutical company is required by law to report each episode of an adverse reaction after it learns of its occurrence, there is no wisdom in the contention that fear of liability would preclude such disclosure. The disclosure is mandated.

Accordingly, if the pharmaceutical manufacturer and distributor has knowledge of adverse reactions and frankly and fully discloses such knowledge in accordance with law, there should be no reluctance to warn the medical profession by means of a package insert or PDR article of such adverse reactions.

Of course, this does not happen in reality, for the drug producers are more interested in sales than in warnings. We only have to examine Exhibits 29, 30, 34, 35, 42, 52 and 53 to learn that the

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interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person having charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

men in Upjohn's adverse reaction or drug experience section were thoroughly familiar before 1970 with those palliative measures for reducing the colitis which finally appeared in the 1974 warning section, four years after Dr. Smyth had taken the drug.

Still, the public policy argument falls because they were under the obligation of full disclosure. Their failure in some instances to make full disclosure is not material to the public policy issue. Virtue is not inhibited by the necessity to disclose what they already know, for they are bound to disclose it at any cost.

There are exceptions to the subsequent repair doctrine. It is no longer applied in cases of strict liability in tort and implied warranty.

Sutkowski v. Universal Marion Corp., 5 Ill. App. 3d, 313, 281 N.E. 2d 749 (1972)

Ault v. International Harvester Co., 117 Cal. Rptr. 812 (Sup. Ct. Calif. in bank, Dec. 12, 1974)

In Ault plaintiff claimed a defective gear box made of aluminum 380 and attached to a vehicle in which he was riding was responsible for the accident in which he was injured. A California statute provided, "When, after the occurrence of an event, remedial or precautionary measures are taken, which, if taken previously, would have tended to make the event less likely to occur, evidence of such subsequent measures is inadmissible to prove negligence or culpable

conduct in connection with the event."

At the trial it was established that after the accident defendant changed from aluminum 380 to malleable iron in the production of the gear box.

Plaintiff's experts testified that the aluminum 380 was not a suitable material for the gear box and that malleable iron was stronger and more effective for this purpose.

In the case at bar, plaintiff's expert would have testified that the PDR article existing in February 1970 was insufficient to warn plaintiff what was in store for him if he were to become the victim of Lincocin-induced colitis (offer of proof made on January 22, 1975; Appendix pp. 1-10).

In Ault plaintiff's experts testified that three years after the accident, defendant substituted malleable iron for aluminum 380 in the manufacture of the gear box.

In the case at bar, plaintiff would have proved that after February 1970 -- in fact, the following July -- defendant added the words "acute colitis" to the warning section of the PDR article, and that with successive years the warning became more pronounced until in 1974 it actually contained remedial prescriptive meansures for combating the colitis.

The Court held in Ault that it would have been an extension of the exclusionary rule if it were applied to cases of strict liability.

In the case at bar, although not one of strict liability, the rationale is the same. The public policy prop having fallen, the rule, too, must fall in the light of reason and modern merchandising techniques of complicated machinery and potentially dangerous drugs.

The trend in New York is clearly set by Codling v. Paglia, 32 N.Y. 2d 342, 345 N.Y.S. 2d 461 (1973) where the burden is placed squarely upon the manufacturer of a complicated piece of machinery to rebut the inference of its defect.

Historically, the subsequent repair doctrine was developed with reference to the usual negligence action in which a pedestrian fell into an unfenced hole (e.g. Corcoran v. Village of Peekskill, supra). In such a situation it would be reasonable to assume that the landowner -- so often favored by the Common Law -- might be deterred from making repairs because such repairs could be used against him in determining liability for the initial accident.

> "When the context is transformed from a typical negligence setting to the modern products liability field, however, the 'public policy' assumptions justifying this evidentiary rule are no longer valid. The contemporary corporate mass producer of goods, the normal products liability defendant, manufactures tens of thousand of units of goods; it is manifestly unrealistic to suggest that such a producer will forgo making improvements in its product, and risk innumerable additional lawsuits and the attendant adverse effect upon its public image, simply because evidence of adoption of such improvements may be admitted in an action founded on strict liability for recovery on an injury that preceded the improvement. In the products liability area, the exclusionary rule of section 1151 (California Code of Evidence re. subsequent repairs) does not affect the primary conduct of the mass producer of

goods, but serves merely as a shield against potential liability..."

Ault v. International Harvester Co., 117 Cal. Rptr. 812, 815-16.

So with the drug manufacturer, the assumption that the admission in evidence of subsequent more forceful warnings of dangerous side effects discourages the manufacturer from giving the necessary warnings may be erroneous. They may not be so callous to the safety of the consumer as the general exclusionary rule presumes. Furthermore, to the extent that admission of such evidence results in recovery by injured plaintiffs, it can be argued the evidence of subsequent repairs encourages future remedial action. Also, concern on the part of the distributors for consumer protection is promoted by consumer organizations, federal agencies (FDA), and mass media exposure of harmful drug reactions. To some extent, the economic self-interest of drug distributors requires that they give full and complete warnings of the harmful side effects of their drugs to avoid adverse publicity which might result from future litigation or legislative action. (The foregoing paragraph is parphrased from "Products Liability and Evidence of Subsequent Repairs" Duke Law Journal, Vol. 1972, No. 4, p. 837 at pp. 848 and 849.)

Moreover, the question of relevancy is overcome by the numerous examples of acute colitis which were reported to defendant prior

to 1970 (Appendix - Exhibits 16-65) the date of the accident. It is pointed out in the old cases that the negligence which fixes liability depends upon what defendant knew before the accident and must be established by facts which preceded it, and not by acts performed by him after the occurrence.

Here ample knowledge of serious side effects from Lincocin were in defendant's files up to February 1970. In fact, far less than six months experience following that date must have gone into the warning of July 1970 -- the first to mention "acute colitis." The article must have been composed by defendant and submitted to the FDA for approval well in advance of publication.

Since the strengthening of the warning came so closely upon the heels of the accident, evidence of the subsequent warning is admissible upon the further ground that it illustrates the feasibility of the improved warning at the time of the accident itself.

Ault v. International Harvester Co., 117 Cal. Rptr. 812, 815 and cases there cited.

In the leading Pennsylvania drug case (Chloromycetin) Incollingo v. Ewing, 444 Pa. 263, 282 A2d 206 (1971), the trial court admitted over objection, evidence of a subsequent warning employed in the drug company's literature after the drug had been prescribed for the plaintiff. The court stated at 282 A2d 222, 233:

"...Although precautions taken after the acts complained of are inadmissible for the purpose of proving antecedent negligence, Baran v. Reading Iron Co., 202 Pa. 274, 51 A. 979 (1902), such evidence is admissible if competent for any purpose and as long as it is so qualified by instructions to the jury. Hyndman v. Pa. Railroad Company, 396 Pa. 190, 152 A2d 251 (1959). In the latter case it was held that evidence of the type here in issue is admissible "to show a caution which was not costly or burdensome to the defendant in relation to the risk or danger involved." Id. at p. 200, 152 A2d at p. 256. The charge in this case clearly instructed the jury that the subsequent warning "was admitted for the limited purpose to show a caution which was not costly or burdensome to Parke, Davis in relation to the risk or danger involved." The jury was thrice instructed that the 1961 warning was not to be taken as evidence bearing on antecedent negligence. Parke, Davis nevertheless takes exception to the following portion of the charge: "You may ask yourselves whether knowing that, whether having changed the warning in 1961 is the warning that they should have been fully aware of in 1960 and prior thereto (sic). You may use that as evidence of the fact that they knew or should have known, and could have used that warning which they used in 1961 back in 1960, 1959, and 1958." In reviewing this instruction, "we must look to the charge in its entirety to determine whether or not error was committed and whether

that error was prejudicial." Mount v. Bulifant, 438 Pa. 265, 265 A2d 627 (1970). We are of the opinion that the charge, taken as a whole, adequately qualified the jury's consideration of this evidence, and cannot say that the quoted language, while it went too far, was prejudicial."

It is our contention that Upjohn had ample notice before February 3, 1970, the date Dr. Smyth took the drug, that it could produce "acute ulcerative colitis," "ulcerative colitis," and a severe form of undefined colitis, all of which produced symptoms manifested by Dr. Smyth.

The notice which Upjohn received was in the form of "adverse reaction reports" received from physicians who had been using Lincocin on their patients with a resultant fulminating serious form of colitis far transcending the "cases of severe and persistent diarrhea, some with blood and mucus in the stool...(which) have necessitated discontinuance of the drug." The latter words are those used in the 1970 PDR at page 1385. These reports were received from all over the United States and exceeded 50 in number. Upjohn also had notice of this condition from articles published in medical journals or papers read at medical conventions prior to February 3, 1970.

It is our contention that in the light of what Upjohn knew on or before February 3, 1970, it should have used the same warning

it was finally compelled to issue in 1974. It is our contention that in addition to specifying "pseudomembranous colitis" Upjohn should have been required to mention "acute ulcerative colitis."

Certainly, the changes in printed package inserts and the PDR articles which would entail some editing and printing would demonstrate a "caution which was not costly or burdensome to the defendant in relation to the risk or danger involved."

Rule 407 of the new Federal Rules of Evidence is declaratory of the general rule such as that above cited in Ault. It is, however, subject to the usual exceptions.

"Understanding the New Federal Rules of Evidence," Rothstein, 1973 Ed. pp. 27-29.

We again urge upon this Court the adoption of a further exception in an antibiotic drug product liability case.

POINT II

THE JUDGMENT BELOW SHOULD BE REVERSED.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
For the Second Circuit

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

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MALACHY J. SMYTH and LUCY SMYTH, :

Plaintiffs-Appellants, :

AFFIDAVIT OF SERVICE

vs. :

Docket No. 75-7143

THE UPJOHN COMPANY, :

Defendant-Appellee. :

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STATE OF NEW YORK )
SS.:
COUNTY OF ONEIDA )

HELEN S. COUPE, being duly sworn, deposes and says: I am over 18 years of age. That I duly and personally served Kernan and Kernan, attorneys for the defendant-appellee in the above matter by leaving two copies of the appendix and two copies of the brief with the receptionist in charge of their office whose name is Mary Litte on the 28th day of May, 1975, at 11:25 a.m.

Helen S. Coupe

Helen S. Coupe

Sworn to before me this
28th day of May, 1975.

Suzanne L. Shaw

SUZANNE L. SHAW
Notary Public in the State of New York
Appointed in Oneida County
My Commission Expires March 30, 1977

STATE OF NEW YORK, COUNTY OF ss.: **INDIVIDUAL VERIFICATION**

, being duly sworn, deposes and says that deponent is the in the within action; that deponent has read the foregoing and knows the contents thereof; that the same is true to deponent's own knowledge, except as to the matters therein stated to be alleged on information and belief, and that as to those matters deponent believes it to be true.

Sworn to before me, this day of 19 .....

STATE OF NEW YORK, COUNTY OF ss.: **CORPORATE VERIFICATION**

, being duly sworn, deposes and says that deponent is the of the corporation named in the within action; that deponent has read the foregoing and knows the contents thereof; and that the same is true to deponent's own knowledge, except as to the matters therein stated to be alleged upon information and belief, and as to those matters deponent believes it to be true.

This verification is made by deponent because is a corporation. Deponent is an officer thereof, to-wit, its

The grounds of deponent's belief as to all matters not stated upon deponent's knowledge are as follows:

Sworn to before me, this day of 19 .....

Sir: Take notice of an..... .....

.....

of which the within is a true copy, was duly granted in the within entitled action, on the.....

.....day of

.....19 , and duly entered in the office of the Clerk of the County of

.....on the

.....day of.....19

Dated....., N. Y.

.....19

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To.....

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UNITED STATES COURT OF APPEALS
STATE OF NEW YORK
For the Second Circuit

UNITED STATES DISTRICT COURT
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